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Discussion

Mr Cliff K. Choong *(Cambridge, United Kingdom)*. Congratulations on your very good study and results. Based on this, have you changed your practice to use this device for all your subsequent patients?

Dr Corno. First of all, we now can use this device in any patient because the hospital administration is convinced that, despite the initial cost, we can spare the money.

Regarding the management, we changed a lot of policies. For instance, patients with multiple ventricular septal defects are now, in the neonatal period, treated with this device. Now we have a group of 5 patients, on average 2 to 3 years after surgical intervention, and we follow all of them. Of course, when the patient grows and the body weight increases, we can release the device to avoid the right ventricular pressure becoming suprasystemic. And in 4 patients all multiple ventricular septal defects, 2½ to 3 years after surgical intervention, underwent spontaneous closure. Two weeks ago, I operated on one patient, removing the device, and without anything else required, even the pulmonary artery reconstruction was not necessary. Much easier is the management, of course, of a univentricular heart, for obvious reasons, because you can titrate the distal pulmonary artery pressure as you want based on echocardiographic results. In the group for left ventricular retraining, we have only 4 patients, but the number is increasing and, of course, in the future, with this device available for left ventricular retraining.

Mr Choong. Second, do you recommend that all pediatric surgeons should now be using this rather than conv-PAB?

Dr Corno. Yes. It changes from the night to the day.

Mr Choong. Lastly, the device seems to be flawless. Are there any short- or long-term complications associated with this device?

Dr Corno. We have found complications with this device caused by the fact that the piston is covered by a silicone membrane to prevent damage to the pulmonary artery. We had one complication in one of the animals in the clinical study and in 2 patients, one in another center and one in our center, because if you go close to the membrane with any sharp instrument, like a needle or knife, you can produce a hole in the membrane, the pericardial fluid enters into the device, and then the micromotor stops working. Then you remain with a conventional banding.

Dr Renato Assad *(Sao Paulo, Brazil)*. First of all, I would like to congratulate Dr Corno and his colleagues for the very ingenious FloWatch and his work on adjustable PAB.

I would like to share with the association the first case in which a high-risk neonate with hypoplastic left heart syndrome was initially managed with a miniadjustable PAB system in both pulmonary arteries. The banding system is entirely silicone covered, a miniaturized and improved device developed from our previous experimental studies that resulted in a more delicate banding system for neonatal use with a 4-mm diameter. Ten percutaneous adjustments of the banding system were necessary to keep the arterial oxygen saturation in the 75 to 85 range before the second stage. The Norwood operation and bidirectional Glenn shunt were carried out on the 106th day of life, and the total cavopulmonary connection was carried out in the 21st month of life. There was no pulmonary artery distortion after removing the bands.

The clinical use of this innovative PAB system allowed for a customization of the pulmonary blood flow according to the underlying clinical needs, resulting in a more precise balance between the pulmonary and systemic circulations.

I have a question for Dr Corno regarding the left ventricular retraining patient. How was the length of time comparing the 2 systems?

I thank the association for the opportunity to make these comments about your new prototype.

Dr Corno. Thank you, Dr Assad, for the question. Of course I am familiar with your article, and I can tell you at the moment that there is no indication of using this device when you need a bilateral banding. The first reason is the size of the device, and the second is the cost. You will need to do another study and have discussions with the hospital administrators.

To answer your question, the interval depends on the adaptability of the new system. We follow this with echocardiography, and we want, of course, to obtain almost systemic pressure in the new systemic ventricle. From a study done when I was in Lausanne,[11] we calculated with the echocardiographic analysis the ratio between the thickness of the free wall of the right ventricle versus the left ventricle. When you have reached the inversion of the ratio, it means that we have reached a high enough level of left ventricular hypertrophy or hyperplasia according to the age of the child, and then we can go for the arterial switch operation.

Dr Pedro Becker *(Santiago, Chile)*. That was very interesting, Antonio, but what bothers me is that I do not find here the key end point that you are pursuing when you band the pulmonary artery. To me, mortality is such a gross end point. Pulmonary artery bands are designed to either decrease pulmonary artery pressure, limit Qp/Qs, or retrain the left ventricle. Therefore I think it would be very interesting to really know whether the goals of the PAB were properly accomplished with this device in a better way than the conventional technique and therefore convince us surgeons not to use just the regular PAB any more. Congratulations, anyway.

Dr Corno. Thank you. First of all, you can discuss the indication for banding versus repair. These patients, in our experience, were without indication for a repair because either they were in for a univentricular type of repair (and you cannot perform a cavopulmonary connection in the first weeks of life) or in for left ventricular retraining. In case of biventricular repair, we had patients with unbalanced complete atrioventricular septal defect, multiple ventricular septal defects, ventricular septal defect with aortic coarctation, and hypoplasia of the aortic arch. Most patients were referred after 1 or 2 months in the ICU on mechanical ventilation. In our experience these patients did not constitute a good indication for banding. Then you have to decide between a conventional banding and an adjustable banding. The main difference is the management in the immediate postoperative course.

With a fixed band, either you have to go back and reopen the chest 2 or 3 times, particularly when you need for univentricular heart or left ventricular retraining, whereas with this device you can simply go in the operating room, perform a much faster procedure, and clip the band and close the chest, and you do all the adjustments after the operation. You can do it progressively within days or weeks, and this is much better tolerated than the conventional banding, when you have to suddenly change the hemodynamics.